SCOPE OF WORK

RISK ANALYSES AND REPORTS ON THE OPERATION OF THE BOSTON UNIVERSITY MEDICAL CENTER NATIONAL EMERGING INFECTIOUS DISEASES LABORATORIES

TASK ORDER NO. 0015
CONTRACT NO. W91278-08-D-0017

August 2008

1.0 BACKGROUND: In 2003, following a peer-review process, Boston University Medical Center (BUMC) was awarded a grant from the National Institute of Allergy and Infectious Diseases for the construction of a National Biocontainment Laboratory (NBL), known as the National Emerging Infectious Diseases Laboratories (NEIDL), to provide essential infrastructure for congressionally mandated programs of biodefense research. The NEIDL will include biosafety level 2, 3, and critically needed biosafety 4 (BSL-4) research space.

As a prerequisite to the facility's construction, the Massachusetts Executive Office of Energy and Environmental Affairs (MEOEEA) required BU to prepare a Final Environmental Impact Report (FEIR) for Biosquare Phase II, the future proposed site of the NEIDL to satisfy the requirements of the Massachusetts Environmental Policy Act (MEPA). In accord with the National Environmental Policy Act (NEPA), the National Institutes of Health (NIH) completed a Final Environmental Impact Statement (FEIS) for the BUMC NEIDL in December 2005 and published a Record of Decision in February 2006. Public input and comments were solicited, received, and considered throughout the process. In preparing the FEIS, the NIH thoroughly reviewed the possible impacts of the BUMC NEIDL on the public and the environment and concluded that the construction and operation of the BUMC NEIDL posed negligible risk to the community in which the laboratory was sited or to the surrounding communities. Construction of the BUMC NEIDL is underway at the BioSquare II Research Park on Albany Street in Boston, adjacent to the Boston University Medical Center.

Under both State and Federal environmental policy laws, the public must be provided with an opportunity to review and comment on the assessments. Some residents and community groups have raised objections to the construction of the BUMC NEIDL and to the analyses of potential environmental impact. Lawsuits were filed by these groups in State court (July 29, 2005) and Federal court (May 18, 2006).

In response to specific concerns raised in Federal court, the NIH prepared a Draft Supplementary Risk Assessments and Site Suitability Analyses (DSRASSA) for the BUMC NEIDL. The DSRASSA focused on potential impacts of the release of several Biosafety Laboratory Level 4 (BSL-4) agents into the community under various scenarios. The DSRASSA was released for public comment in August 2007.

In July 2006, the Massachusetts Superior Court held that BUMC's FEIR failed to consider any "worst case" scenario that involved the risk of contagion arising from the accidental or malevolent release of a contagious pathogen from the BUMC NEIDL and that the FEIR failed to analyze whether the "worst case" scenario would be materially less catastrophic if the NEIDL

were located in a feasible alternative location in a less densely populated area. The judge voided the MEOEEA's approval of the FEIR, and the state agency required BU to submit a supplemental FEIR (SFEIR) to address these shortcomings. The Massachusetts Supreme Judicial Court upheld the trial court's decision voiding the approval of the FEIR in December 2007. The MEOEEA asked the National Research Council (NRC) to analyze the DSRASSA because the state agency viewed the DSRASSA as potentially relevant to its decision- making process. The NRC issued a report in November 2007 highly critical of the analytic approach used in the draft supplemental analysis.

To guide the agency in responding comprehensively to judicial requests and public concerns, NIH established a Blue Ribbon Panel of independent experts to advise the NIH on the scope of any additional risk assessments that might be necessary. With these findings and directives in mind, the Panel reviewed the previous risk assessments of the siting and operation of the NEIDL as well as judicial materials and public input. They concluded that additional studies should be performed in order to address the judicial requests and concerns of the public and that the studies should include an array of microbial agents that differ in terms of infectivity, pathogenicity, and transmissibility. The Panel further noted that the studies should employ methodologies that have been validated and accepted by the scientific community; incorporate epidemiologic data; factor in the characteristics of the community surrounding the NEIDL; and be transparent in terms of assumptions, sensitivity of methods, final results, and interpretation of results.

2.0 SCOPE OF WORK: This Scope of Work (SOW) is for the Architect-Engineer (A-E), also referred in this SOW as Tetra Tech Inc. to provide expertise, technical, and administrative support in the preparation of additional risk analyses and site comparisons for the BUMC NEIDL in Boston, Massachusetts as specified in **Enclosure 1.** These additional risk analyses will assess potential risks and public health consequences of accidental and malevolent releases of infectious agents and exposure to infectious agents in urban versus less populated locations.

3.0 OBJECTIVE: The principal objective of this effort is to provide the NIH with a Risk Assessment (RA) Report that is a complete and objective appraisal of the potential risks and public health consequences of accidental and malevolent releases of infectious agents and exposure to infectious agents in urban versus less populated locations.

The RA Report shall comply fully with NIH requirements, both procedurally and analytically, and is intended to be sufficient to withstand a challenge in Federal court. The NIH is the customer, but the U.S. Army Corps of Engineers (USACE), Mobile District will be designated as the "Government" in this SOW. USACE, Mobile District will assist the NIH to monitor, review, guide, and approve the A-E's work products.

4.0 SITE COMPARISONS: The areas for risk analyses for site comparisons are: (1) Boston University Medical Center, BioSquare Research Park, Boston, MA; (2) Boston University Corporate Education Center, Tyngsborough, MA; and (3) Boston University Sargent Center for Outdoor Education, Peterborough, NH. The site-specific risk assessment reports will characterize the relative risks for a given site and the comparative assessment will include an analysis of the relative risks across the sites. (NOTE: comparable facilities are being built on all three sites.)

5.0 DESCRIPTION OF WORK AND SERVICES (Risk Analyses): Enclosure 1 describes the work and services specified by this SOW for preparation of additional risk analyses and site comparisons.

ENCLOSURE 1

DESCRIPTION OF WORK AND SERVICES

1.0 INTRODUCTION:

a. Management/Approval. The NIH has designated the USACE, Mobile District to contract for and assist with the oversight of the risk analyses preparation of this Report. The Architect-Engineer (A-E), also referred in this SOW as Tetra Tech Inc. will take technical and administrative guidance from the Mobile District. Both the A-E and the Mobile District work for the NIH.

b. Labor, Materials and Equipment. The A-E shall furnish all labor, materials, plant, equipment, and transportation (including mail or facsimile fees) to perform all work and services in accordance with the requirements of this SOW.

c. Data Management. All data, reports, and materials contained or developed in this project will not be released to the public without written approval from NIH and USACE, Mobile District technical manager(s).

2.0 METHODOLOGY DEVELOPMENT:

Overall descriptions of Tasks for each of the three sites ([1]Boston University Medical Center, BioSquare Research Park, Boston, MA; [2] Boston University Corporate Education Center, Tyngsborough, MA; and [3] Boston University Sargent Center for Outdoor Education, Peterborough, NH) considered are as follows:

- Develop conceptual risk model(s)

The conceptual risk model is developed to identify the data that are needed to appropriately characterize sources of pathogens, release mechanisms, release routes, exposure pathways, and potential receptors, hosts, and vectors. All available site information is compiled and analyzed in order to develop the conceptual model. Collection and analysis methods are identified for all data that are not readily available. The conceptual risk model provides the definition of the objectives of the overall risk assessment including investigations and the identification of data gaps. The identification of potential exposure pathways, including potential exposure points, is a key element in the determination of data needs for the risk assessment. The elements of a Conceptual Model are presented in **Exhibit 1**.

a. Source term
b. Release mechanisms
c. Transport and Exposure pathways
d. Consequence modeling (spread and growth of disease for each specific pathogen)

- Data collection and evaluation
- Identify hazards/accident/security events (wide range – typically several hundred potential hazard – accident scenarios are qualitatively evaluated)

- Rank hazard/accident scenarios to select a subset of unique and representative accident scenarios for detailed evaluation (in accordance with **Exhibits 2 and 3** and modified with additional events/scenarios)
- Select the subset of representative accident/release scenarios
- Perform quantitative analysis of accidents analysis
    a. Use standard industry approaches and include both mitigated and unmitigated accidents to ensure appropriate consideration of potential prevention and mitigation strategies
    b. The methods will include as appropriate use of event and fault trees, monte-carlo uncertainty analyses, statistical evaluations etc.
    c. Techniques are applied to source term, release mechanisms, transport, and exposure or consequence modeling to address spread and growth of disease – pathogen specific
    d. The detailed analysis will include an evaluation of both the security and safety system response and vulnerability based on each release scenario
- Exposure and Consequence Assessment (evaluation of results from modeling using qualitative and quantitative modeling as appropriate)
    a. Release mechanisms, sources, and magnitudes (including potential for being *aerosolized)*
    b. Transport Analysis
    c. Exposure
- Pathogen Hazard Potential (pathogenicity or transmissibility, virulence, resistance to treatment, availability of vaccines, ability to be *aerosolized,* etc.)
    a. Agents included at a minimum are:
        - 1918 pandemic influenza virus
        - *Yersinia pestis*
        - *Francisella tularensis*
        - *Bacillus anthracis*
        - SARS-associated coronavirus
        - Rift Valley fever virus
        - Andes hantavirus
        - Junin haemorrhagic fever virus
        - Tick-borne encephalitis complex virus (Russian spring-summer encephalitis)
        - Lassa fever virus
        - Marburg virus
        - Ebola virus

- Risk Characterization and Presentation
    b. Likelihood
    c. Consequence
    d. Comparative analysis
    e. Prevention and Mitigation Strategies, including emergency response
        - Vulnerability Assessment
            - Intentional Acts, including those with malevolent intent
            - Accidents

3.0 SERVICES REQUIRED:

TASK 1. Prepare a Project Management Plan (PMP) and Schedule. The A-E shall prepare and submit a Draft PMP and schedule **10 working days** after receipt of the Notice to Proceed. The PMP will specify dates on which all deliverables are to be submitted to the NIH and USACE and indicate the sequence of work for preparing the Risk Assessment Work Plan (RAWP) and Risk Assessment (RA) Report.

The Draft and Final PMP will include at a minimum a, breakdown of supervisory controls within the company, listing of assigned A-E staff and resumes for those who are responsible for completion of various tasks under this Task Order, quality assurance plan for deliverables, and a schedule of the deliverables and timeline for completion that will be used by the A-E to manage work. The NIH and USACE, Mobile District will use this schedule to monitor work progress and base interim payment decisions on the percent of completed work reported on the billing. The schedule will highlight the dates that specific milestones will be met. The NIH and USACE will provide comments on the Draft PMP within **5 working days** following receipt of the Draft PMP. The A-E will prepare and submit the Final PMP **5 working days** after receipt of comments from the NIH and USACE, Mobile District.

Deliverables for Task 1 – An electronic copy and as many as five (5) hard copies of the Draft and Final PMP and Schedule for the NIH and two (2) hard copies for the USACE, Mobile District.

TASK 2. Conduct a Kick-off Meeting. Within **15 working days** of the Notice to Proceed, the A-E with appropriate personnel will attend and participate in the initial meeting with the NIH Project Officer and additional NIH representatives, as designated by the NIH Project Officer, and USACE, Mobile District on the NIH Campus in Bethesda, MD. The purpose of the meeting is to discuss and agree upon a plan and timeline for this project. Also, the meeting will provide the A-E an opportunity to present concepts of the RAWP. The meeting will be chaired by NIH and include possible participation by members of the Blue Ribbon Panel. The A-E must be prepared to fully participate and lead a discussion of the timeline and plan to accomplish this project, as well as present concepts of the RAWP.

Deliverables for Task 2 – Electronic Kick-off Meeting Agenda for NIH and USACE, Mobile District.

TASK 3. Prepare a Risk Assessment Work Plan (RAWP). The A-E shall prepare the RAWP; the RAWP will be the primary management tool for the project. The project will be comprised of four distinct phases and will be directly related to the procedure for preparing the RA Report. The RAWP will include details on the deliverables at each phase of the project.

The A-E shall submit the Draft RAWP 30 days after the Notice to Proceed.

Deliverables for Task 3 – An electronic copy (CD) and as many as ten (10) hard copies of the Draft RAWP and Final RAWP for NIH, ten (10) hard copies for a subset of the Blue Ribbon Panel, and two (2) hard copies for USACE, Mobile District. The NIH shall have two (2) weeks

to review and comment on the Draft RAWP. The A-E shall conduct a face-to-face In-progress Review (IPR) with NIH, Blue Ribbon Panel, and USACE, Mobile District at the NIH office located in Bethesda, MD at the end of the review time for the Draft RAWP. The A-E will revise the Draft RAWP to incorporate comments and provide a single Check Copy Final RAWP for NIH and USACE (depending on the nature of the comments the RAWP will require a minimum of four (4) weeks for revision to include conducting a face-to-face IPR with NIH, Blue Ribbon Panel, and USACE, Mobile District at the NIH office located in Bethesda, MD). The NIH shall have one (1) week to review the Check Copy Final RAWP. The A-E will revise the Check Copy Final RAWP as necessary and submit an electronic copy and twenty (20) hard copies of the Final RAWP to NIH and USACE, Mobile District.

TASK 4. Prepare 25% Draft Risk Assessment (RA) Report. The A-E will address the following for this Task:

- Conceptual Model
- Data collection and evaluation
- Identification of Methods, Models, Assumptions, and Validation Method
- Identification and Evaluation of Hazard/Accident/Security Scenarios
    - Includes evaluation of security and safety system vulnerability
- Selection of Accidents for detailed analysis

The A-E shall submit the 25% Draft RA 1.5 months after approval of the RAWP.

Deliverables for Task 4 – An electronic copy (CD) and as many as ten (10) hard copies of the 25% Draft RA will be provided to the NIH, ten (10) hard copies for a subset of the Blue Ribbon Panel, and two (2) hard copies for the USACE, Mobile District. The NIH shall have two (2) weeks to review and comment on the 25% Draft RA. One (1) week after receipt of comments the A-E will conduct one (1) telephonic IPR with NIH and USACE, Mobile District.

TASK 5. Prepare 50% Draft Risk Assessment (RA) Report. The A-E shall address the following for this Task:

- Quantitative analysis of selected accidents (and intentional events)
- Source Term Analysis
- Release Mechanisms
    - Detailed analysis of security and safety system response
- Transport Models (qualitative and quantitative analysis)

The A-E shall submit the 50% Draft RA 3.5 months after approval of the RAWP.

Deliverables for Task 5 – An electronic copy (CD) and as many as ten (10) hard copies of the 50% Draft RA will be provided to the NIH, ten (10) hard copies for the subset of the Blue Ribbon Panel, and two (2) hard copies for the USACE, Mobile District. The NIH shall have two (2) weeks to review and comment on the 50% Draft RA. One (1) week after receipt of comments the A-E will conduct one (1) telephonic IPR with NIH and USACE, Mobile District.

TASK 6a. Prepare 75% Draft Risk Assessment (RA) Report. The A-E will address the following for this Task:

- Accident Analysis includes for both uncontrolled and controlled:
- Likelihood of agent release, transport, and exposure
- Consequences for each pathogen
- Uncertainty analysis
- Prevention and mitigation strategies
    - Vulnerability Assessment
        - Accidents
        - Intentional Acts, including those with malevolent intent
- Comparative risks at urban, suburban, and rural sites

The A-E shall submit the 75% Draft RA 5.5 months after approval of the RAWP.

Deliverables for Task 6a – An electronic copy (CD) and as many as ten (10) hard copies of the 75% Draft RA will be provided to the NIH, ten (10) hard copies for the subset of the Blue Ribbon Panel, and two (2) hard copies to the USACE, Mobile District. The NIH shall have two (2) weeks to review and comment on the 75% Draft RA. One (1) week after receipt of comments the A-E will conduct one (1) telephonic IPR with NIH and USACE, Mobile District.

TASK 6b. Update "Report on Biosafety at BSL-3 and BSL-4 Laboratories" by Karl M. Johnson, MD. The A-E shall update Dr. Johnson's report to be current through June 2009. The Updated "Report on Biosafety at BSL-3 and BSL-4 Laboratories" will be assembled in one report. This report will be incorporated into the RA Report.

Deliverable for Task 6b – An electronic copy (CD) and as many as ten (10) hard copies of the Updated Draft and Final "Report on Biosafety at BSL-3 and BSL-4 Laboratories" will be provided to NIH and two (2) hard copies to the USACE, Mobile District. NIH and USACE, Mobile District shall have two (2) weeks to review and comment on the Draft Report. The A-E will incorporate comments on the Draft Report and provide a single (electronic and hard copy) Check Copy Final "Report on Biosafety at BSL-3 and BSL-4 Laboratories" for a one (1) week review by NIH and USACE, Mobile District to ensure that all of the comments were satisfactorily incorporated. Once the "Report on Biosafety at BSL-3 and BSL-4 Laboratories" has been approved the A-E will submit the requisite number of copies of the Final Report to NIH and USACE, Mobile District.

Task 7. Prepare 90% Check Copy Draft Final Risk Assessment (RA) Report and a 90% Draft Final Risk Assessment (RA) Report, and Attend and Participate in a Risk Assessment (RA) Public Meeting. The A-E will prepare a 90% Check Copy Draft Final RA Report for a two (2) week review by NIH, Blue Ribbon Panel, and USACE, Mobile District. The A-E will incorporate comments upon recommendations from NIH and produce the 90% Draft Final RA Report which NIH will release to the public for a 45-day review and comment period. The A-E will participate in the NIH sponsored RA public meeting for the review of the 90% Draft Final RA Report. The public meeting will be scheduled by and with logistical support provided by NIH. NIH will make an opening statement at the public meeting to be followed by a presentation of the RA by the A-E.

The A-E shall submit the 90% Check Copy Draft Final RA Report, 90% Draft Final RA Report, and participate in a RA public meeting 7.5 months after approval of the RAWP.

Deliverables for Task 7 – An electronic copy (CD) and as many as twenty (20) hard copies of the 90% Check Copy Draft Final RA Report will be provided to NIH, ten (10) hard copies to the Blue Ribbon Panel, and two (2) hard copies to the USACE, Mobile District. An electronic copy (CD) and as many as one hundred (100) hard copies of the 90% Draft Final RA Report will be provided to the NIH and Blue Ribbon Panel, and two (2) hard copies to the USACE, Mobile District. Also, the A-E will attend and participate in the NIH public meeting by presenting at the public meeting the findings of the RA and the implications.

Task 8. Prepare 100% Check Copy Final Risk Assessment (RA) Report (including the Executive Summary). The A-E shall compile (within 20 working days of the conclusion of the public comment period and depending on the number and nature of the comments) in a matrix the comments received from the public and the applicable agencies. The A-E shall conduct a face-to-face IPR with NIH, subset of the Blue Ribbon Panel, and USACE, Mobile District at the NIH office located in Bethesda, MD to determine how comments received on the Draft Final RA Report will be incorporated into the Check Copy Final RA Report. The A-E shall incorporate comments upon recommendations from NIH.

The A-E shall submit the 100% Check Copy Final RA Report 1.5 months after formal public comment period is complete (mimimum of 45-day public comment period).

Deliverables for Task 8 – The A-E shall compile a matrix of comments received from the public and the applicable agencies, conduct a face-to-face IPR, incorporate comments as per recommendation from NIH, and produce the 100% Check Copy Final RA Report for review by NIH, subset of the Blue Ribbon Panel, and USACE, Mobile District that incorporates the comments received on the 90% Draft Final RA Report. The A-E shall provide an electronic copy (CD) and as many as ten (10) hard copies of the Check Copy Final RA to NIH, ten (10) hardcopies to the Blue Ribbon Panel, and two (2) hard copies to the USACE, Mobile District.

Task 9. Prepare 100% Final Risk Assessment (RA) Report. Any comments received on the Check Copy Final RA Report will be incorporated and an approved 100% Final RA Report will be produced for NIH and USACE, Mobile District.

Deliverables for Task 9 –An electronic copy (CD) and as many as twenty (20) hard copies of the NIH approved 100% Final RA Report will be provided to the NIH, Blue Ribbon Panel, and USACE, Mobile District.

4.0 OTHER SERVICES REQUIRED:

a. Reports. The A-E will prepare the report consistent with NIH NEPA standards that addresses the risk assessments and site comparisons conducted for this project. The format will be determined in consultation between the NIH Project Officer and USACE, Mobile District.

b. Additional Studies and Report Requirements. The A-E will work with the NIH Project Officer and the USACE, Mobile District to develop, as found necessary by NIH, additional study and report requirements that would be needed to support the risk assessments. Any such reports (e.g., scientific peer-reviewed manuscript, lay summary) or studies would be separately funded via a modification to the Task Order following agreement by the NIH.

c. Maintain Bibliography of Data and Reference Sources. The A-E will develop and continue to update the bibliography, with data sources and reports noted. The updated and comprehensive bibliography will be incorporated into the final report and a docket with copies of all cited materials submitted to the NIH. The final bibliography will be limited to references used (cited) in the report.

d. Meetings and Reviews. The A-E will meet with the NIH Project Officer and additional NIH representatives, as designated by the NIH Project Officer, for In-Progress Reviews (IPRs) and other necessary meetings at critical points in the process as described in Section 3.0. Due to the short schedule to complete these assessments and reports, conference calls will be held as necessary. The A-E will be responsible for preparing agendas for these meetings, a written meeting synopsis, and comment response matrices for these reviews. All meetings and reviews will be scheduled at a time to be mutually agreed upon in keeping with the overall project completion schedule.

e. Additional Meetings. The Government reserves the right to request meetings with the A-E to review and discuss the progress and to discuss any problems or concerns that may arise. The A-E may also request meetings with the Government. Dates and locations for meetings shall be mutually agreed upon as necessary. Considering the numerous meetings that may be required to address the many complex issues associated with this project, six (6) additional meetings over the period for the project are designated for this purpose.

Should any additional meetings that would require out-of-town travel by the A-E be incurred, the work shall be considered as out-of-scope and require a modification to this Task Order with associated costs to be negotiated.

f. Participate in Bi-weekly Conference Calls. The A-E, in consultation with the NIH Project Officer, will schedule and conduct conference calls on a bi-weekly basis with the NIH Project Officer, other NIH representatives as designated by the NIH Project Officer and USACE, Mobile District. At the discretion of the NIH Project Officer, Blue Ribbon Panel members may also be included on these calls. The NIH will provide the conference call line for these calls. The A-E is expected to have in attendance members of the A-E's team to adequately address the major issues discussed during the meeting. The purpose of these calls is for the A-E to provide updates on progress and provide an opportunity for NIH and the Blue Ribbon Panel members to ask questions and provide input.

g. Attend and Participate in Progress Review Meetings. The A-E, in consultation with the NIH Project Officer and USACE, Mobile District, will schedule and conduct on-site meetings, anticipated to be held in Bethesda, MD. These meetings will be scheduled at critical points during the project period as described in Section 3.0. The A-E is expected to have in attendance

or otherwise available sufficient members of the A-E's team to adequately address the major issues discussed during the meeting.

h. Attend and Participate in Blue Ribbon Panel Meetings. At the discretion of the NIH Project Officer, two (2) meetings may be held during the period of performance with the A-E, NIH, members of the Blue Ribbon Panel, and USACE, Mobile District. These meetings will be for the A-E to present findings of risk assessments, discuss draft reports, and receive input from the Blue Ribbon Panel on these work products.

i. Attend and Participate in a Public Meeting on the 90% Draft Final Risk Assessment (RA) Report (including the Executive Summary). At the discretion of the NIH Project Officer, the A-E will participate in a NIH-sponsored public meeting for the review of the 90% Draft Final RA Report. The public meeting will be scheduled by and with logistical support provided by NIH, in close consultation with the A-E. The public meeting shall be held no earlier than XX days after the notice of availability appears in the *Federal Register*. A designated NIH representative will make an opening statement at the public meeting. The A-E's Project Manager and other key personnel will be present at the public meeting to present the findings of the risk assessments and the implications.

j. Prepare and Manage Schedule for the Project. The A-E, with input from the NIH Project Officer, shall develop a specific milestone schedule to complete the project within the agreed upon timeframe per Section 3.0, TASK 1. The detailed technical plan and project schedule, indicating the critical path(s) of efforts required to complete the project, as outlined in the tasks above, will be submitted by the A-E within 10 working days following the NTP. The NIH Project Officer will approve the schedule or recommend changes within **5 working days** of receipt. The project schedule should reflect the NIH goal to complete the RA Draft Report as soon as reasonably possible, with a target goal for making the draft publicly available in December 2009. This schedule will be used by the A-E to manage work on the project and by the Government to monitor the progress of work on a monthly basis. The schedule will also include specific dates that demonstrate when milestones will be met. A copy of the schedule, with any revisions or updates, and status of the project milestones will be presented in the monthly progress reviews.

k. Background Work. The A-E will use existing data except for specific studies described in this SOW. The NIH Project Officer will furnish project-related information for the proposed action and alternatives. The A-E shall assemble and review existing data, including information contained in the NIH's prior NEPA review for the NEIDL and use existing information from governmental agencies to the maximum extent possible. Throughout the process, pertinent data gaps that have a bearing on the analyses shall be reported to the NIH immediately upon identification. The NIH will provide existing data previously collected for the FEIS (December 2005) and earlier DSRASSA (August 2007).

l. Site Visits/Field Surveys: The A-E will visit the three sites at least once. Additional field surveys, research, or testing agreed to by the Government, will be accommodated by a modification to the Task Order and an equitable adjustment in the Task Order price will be negotiated.

m. Government Property. The Government shall have the right to use and to distribute to other parties the data and software used to perform the work under the Task Order, and the Government shall have ownership of the work performed under the Task Order. Notwithstanding any other provision of the Task Order, the A-E is required to provide any data relied upon in performing the work under this Task Order. The following Federal Acquisition Regulation clauses are incorporated by reference into the terms of the Task Order.

52.227-14, Alternate II.

52.227-18

52.227-19

52.227-23

5.0 TENTATIVE SCHEDULE:

The following tentative schedule identifies the A-E's time following the Notice To Proceed for preparation of the required environmental documentation for the NIH, Blue Ribbon Panel, and USACE, Mobile District. The actual project schedule shall be determined during initial consultation between the A-E, NIH, and USACE, Mobile District.

▪ Task 1 Draft and Final PMP	10 and 20 days
▪ Task 2 Kick-off Meeting	15 days
▪ Task 3 Prepare Draft RAWP	30 days
-NIH, Blue Ribbon Panel, and USACE review Draft RAWP	2 weeks
-A-E Prepares Check Copy Final RAWP	4 weeks
-NIH, Blue Ribbon Panel, and USACE review Check Copy Final RAWP	1 week
-NIH Approves Check Copy Final RAWP	2 days
-A-E Provides Final RAWP	1 week
▪ Task 4 Prepare 25% Draft RA	1.5 mo. after approval of RAWP
-NIH and USACE review 25% Draft RA	0.5 mo. (2 weeks)

- Task 5 Prepare 50% Draft RA — 3.5 mo. after approval of RAWP

-NIH and USACE review 50% Draft RA — 0.5 mo (2 weeks)

- Task 6a Prepare 75% Draft RA — 5.5 mo. after approval of RAWP

-NIH and USACE review 75% Draft RA — 0.5 mo (2 weeks)

- Task 6b Prepare Update on "Report on Biosafety at BSL-3 and BSL-4 Laboratories" NIH and USACE review Draft Update Report — 2 weeks

-A-E incorporates comments

-NIH and USACE review Check Copy Final Update Report — 1 week

-A-E incorporates comments

-A-E provides Approved 100% Final Updated Report — 1 week

- Task 7 Prepare 90% Check Copy and Draft Final RA Reports and Attend RA Public Meeting — 7.5 mo. after approval of RAWP

-A-E Provides a single 90% Check Copy Draft Final RA Report

-NIH, Blue Ribbon Panel, and USACE review single 90% Check Copy Draft Final RA Report — 0.5 mo (2 weeks)

-A-E incorporates comments

-A-E provides Approved 90% Draft Final RA Report — 1 week

-Conduct Formal Public Comment Period — 1.5 mo. (45 days)

- Task 8 Prepare 100% Check Copy Final RA Report period is complete — 1.5 mo. after formal public comment

-A-E Provides single 100% Check Copy Final RA Report

-NIH and USACE Review single 100% Check Copy Final RA Report — 1 week

- Task 9 A-E Prepare Approved 100% Final RA Report — 1 week

All work on this Task Order will be completed NLT June 30, 2010.

6.0 PAYMENT SCHEDULE: A-E payments will not exceed the following percentages:

Approved RAWP	25%
25% Draft RA Report	70%
50% Draft RA Report	80%
75% Draft RA Report	90%
90% Draft Final RA Report	95%
Approved 100% Final RA Report and Updated "Report on Biosafety at BSL-3 and BSL-4 Laboratories"	100%

7.0 MATERIALS AND LABOR:

NIH Furnished Information and Materials:

Documents and other information available to the A-E will include, but not be limited to the materials described below. Unless otherwise noted, one copy of each item will be available to the A-E.

a. A copy of Final Environmental Impact Report for Biosquare Phase II.

b. Aerial Photograph of Sites.

c. Facilities Site Rendering (NOTE: comparable facilities are being built on all three sites)

d. A copy of FEIS for the BUMC NEIDL.

e. A copy of the Draft Supplementary Risk Assessments and Site Suitability Analyses for the BUMC NEIDL.

A-E Furnished Materials and Labor:

a. A-E shall provide all labor, materials, equipment, transportation, and lodging necessary to complete all tasks specified in this SOW.

b. Qualifications of A-E: A-E's professional employees shall have demonstrated expertise in their appropriate field of study and adhere to the highest research standards and ethics of the profession. A-E shall provide or obtain professional and qualified personnel capable of performing all services required.

c. The cost of reproduction of the all deliverables in the quantities specified.

d. Developing and printing film.

e. It is assumed that the A-E already has adequate staff work area(s), telephones, computers and related equipment, facsimile machines, copy machines, microscopes and cameras.

8.0 MISCELLANEOUS REQUIREMENTS:

a. Monthly Progress Reports. The A-E will prepare and submit a monthly progress report to the Government. The monthly progress report will address work on the RAWP, RA Report, and Update on "Report on Biosafety at BSL-3 and BSL-4 Laboratories". This report shall be sent (includes electronically) to the USACE, Mobile District technical manager(s) for the Task Order, NIH, and other designated individuals. The names and addresses of the recipients will be provided to the A-E at the Kick-off Meeting. The monthly report shall contain an accurate, up-to-date account of all work accomplishments and outstanding issues for the RAWP, RA Report and Update on "Report on Biosafety at BSL-3 and BSL-4 Laboratories". This report shall be no longer than three pages and should contain a statement of progress against the schedule developed by the A-E. This report shall be submitted to the Government no later than the 10th day of the next month following the end of the monthly period covered by each report.

b. Centralized File. The A-E will keep detailed records in a centralized file of the information used to prepare the RAWP, RA Report, and Update on "Report on Biosafety at BSL-3 and BSL-4 Laboratories". A record file will be maintained for the installation. The record file will contain all documents, data, analytical tools, and reference materials utilized by the A-E in preparing the RAWP, RA Report, and Update on "Report on Biosafety at BSL-3 and BSL-4 Laboratories". The A-E shall not disclose any Task Order deliverables to the public without prior approval from the USACE, Mobile District and NIH to ensure that disclosure, when appropriate, is made in accordance with the provisions of the Freedom of Information Act, if invoked by the requester. All records and files shall be deemed the property of the Government**.** Record files will be provided to the installation at the completion of work as a portion of the Administrative Record.

c. Administrative Records. The A-E will prepare and assemble a separate Administrative Record for the RAWP, RA Report, and Update on "Report on Biosafety at BSL-3 and BSL-4 Laboratories". The Administrative Record shall be inclusive of all information, and analyses either generated or obtained from other sources, used to support documentation and analyses. A complete Administrative Record is the entirety of the information relied upon within the A-E's possession plus all information in other locations listed in the references used in preparing the RAWP, RA Report, and Update on "Report on Biosafety at BSL-3 and BSL-4 Laboratories". The A-E will organize the information composing the Administrative Record as accessible files, indexed by topic to the extent possible, and submit the record to the NIH. The Administrative Record shall include the bibliography as described in Section 4.0. The USACE, Mobile District technical manager(s) will be notified in writing when this last requirement under the Task Order is accomplished.

d. Memoranda/Action Item List. The A-E shall furnish the Government a memorandum of each meeting held, summarizing the agreements reached along with an updated Action Item List. All memoranda shall be provided within **5 workdays** of the meetings.

e. Editorial Requirements. The draft and final reports shall be printed front and back on recycled paper unless specified otherwise. The size of pages shall be 8.5 by 11 inches, except for foldout maps, charts, or other illustrative material. Each line of each page of draft reports shall be numbered to facilitate review. Type size and the font used must be approved by the Government prior to printing.

f. Computer Software. Document shall be placed on CDs and provided to the Government in the word processing format agreed upon at the Kick-off Meeting. The mailing list shall be saved on CD's and provided to the Government.

g. Court Testimony. In the event of controversy or court challenge, the A-E will make available, as appropriate, expert witnesses who performed work under this Task Order and shall testify on behalf of the Government in support of the findings. If a controversy or court challenge occurs and testimony of expert witnesses is required, a modification to the Task Order will be made and an adjustment in the Task Order price will be negotiated.

h. Release of Data. All data, reports, and materials contained or developed for this project shall not be released or discussed without written approval from NIH and USACE, Mobile District.

9.0 CONTRACTING OFFICER'S REPRESENTATIVE (COR):

The COR will be designated by the USACE, Mobile District, Contracting Officer and will represent the Contracting Officer in those phases of the Task Order specified in the COR appointment letter. The COR is not authorized to change any of the terms and conditions of the Task Order for this project. Any modifications to the Task Order will be completed in writing by the Contracting Officer.

10.0 POINTS-OF-CONTACT:

The NIH point-of-contact for this work is Ms. Kelly Fennington, (301) 435-2051, email: fenningk@od.nih.gov. The USACE, Mobile District technical managers for this work are: Dr. Neil Robison, (251) 690-3018, Cell (410) 320-9410, email: neil.d.robison@usace.army.mil and Mr. Brian Peck, (251) 690-2750, Cell (251)377-4269, FAX: (251) 690-2727, email: brian.e.peck@usace.army.mil

11.0 SUBMISSION AND APPROVAL OF WORK:

a. Within 10 days after date of award of the Task Order, in accordance with Section 3.0, TASK 1 Prepare a PMP and Schedule will be prepared and submitted for approval. The schedule will show that various items included in the Task Order and the order in which A-E proposes to carry

out the work, with dates on which he will start the features of the work and the contemplated dates for completing same. This proposed and actual progress will be updated each month. Significant milestones such as review submittals shall be annotated. Such schedule shall provide for completion of all work within the Task Order time. The A-E shall assign sufficient technical, supervisory, and administrative personnel to ensure the execution of the work in accordance with the approved progress schedule.

b. The A-E shall correct the progress schedule at the end of each month and shall deliver three copies to the USACE, Mobile District technical manager(s). Inasmuch as monthly partial payments to the A-E are based to a large extent on the progress schedule, the monthly corrections should be realistically made to the best ability of the A-E.

c. Review Comments. For each Review Submittal, the A-E will be furnished comments. If the A-E disagrees technically with any comment or comments and does not intend to comply with the comment, he shall clearly outline, with ample justification the reasons for noncompliance within seven (7) working days after receipt of these comments in order that the comment can be resolved. The disposition of the remaining comments shall be furnished in writing with the next scheduled submittal. The A-E is cautioned in that if he believes the action required by any comment exceeds the requirements of this Task Order, he should take no action and notify the USACE, Mobile District technical manager(s) in writing immediately.

d. Needs List. Throughout the life of his Task Order, the A-E shall furnish the NIH and USACE, Mobile District technical manager(s) a monthly "needs' list. This list shall itemize in an orderly fashion data required by the A-E to advance the project in a timely manner. Each list shall include a sequence number, description of action item, and remarks. The list will be maintained on a continuous basis with satisfied action items checked off and new action items added as required. Once a request for information is initiated, that items shall remain on the list until the requested information has been furnished or otherwise resolved. Copies of the list will be mailed to both the NIH and USACE, Mobile District technical manager(s).

e. Payment. Partial payments, as authorized by the COR. will be made monthly for the amount and value of the work and services performed by the A-E in accordance with the General Provision of the Task Order. An updated progress chart will be submitted with each payment estimate (ENG Form 93). ENG Form 93 may be found on the Internet at: http:/www.usace.army.mil/usace-docs/forms/. All ENG Form 93's shall be submitted as hard copies, consisting of the original and five (5) copies, to the U.S. Army Corps of Engineers, Mobile District, Attn: SAMEN-DW (Mary Breland), P.O. Box 2288, Mobile, Alabama 36628. This estimate will be verified by the USACE, Mobile District technical manager utilizing the progress report submitted by the A-E and independent analyses of progress. When submitting for final payment include a Release of Claims Statement on ENG 93. The following statement is acceptable.

"The work under the above number task order having been completed and finally accepted, I hereby release the United States of America, its officers and agents from all claims whatsoever arising under or by virtue of this task order upon payment of a balance due of $_____".

12.0 CONDUCT OF WORK: In performance of Task Orders with the USACE, Mobile District, the A-E shall:

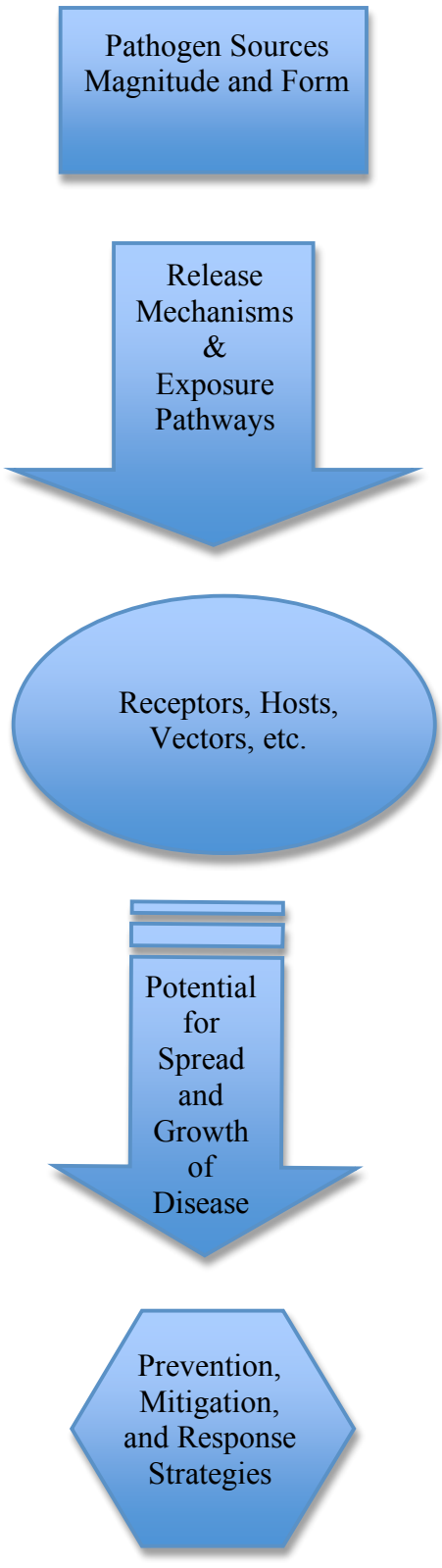
a. Schedules. Make every effort to meet project schedule milestones which were established at negotiations and/or at the beginning of design. In this connection, the A-E will bring to the attention of the technical manager(s) any conflict in criteria, lack of criteria, or any condition that appears to put the project schedule in jeopardy if not resolved.

b. A-E Instructions. The A-E will accept instructions only from the USACE, Mobile District; however, requests or desires of the Using Agency made directly to the A-E shall be forwarded to the District for consideration. Any changes to the Task Order scope must be authorized in writing by the Contracting Officer.

c. A-E Responsibilities. The A-E has complete responsibility for the professional quality, technical accuracy, and coordination of all designs, drawings, specifications, and other work or materials produced and furnished by his in-house and consultant's forces. The A-E shall correct or revise any errors or deficiencies in his work, notwithstanding any review, approval, acceptance, or payment by the Government. Thus the responsibility continues after final payment is made to the A-E. Corrections and changes resulting from review of the A-E's completed work will not be made by the Government but will be returned to the A-E for correction. The A-E shall always be liable to the Government for damages to the Government caused by negligent performance by the A-E.

13.0 PERIOD OF PERFORMANCE: The period of performance for the completion of this Task Order is June, 30, 2010.

EXHIBIT 1: ELEMENTS OF A CONCEPTUAL MODEL



	Variables	**Hypotheses to be Tested**
Pathogen Sources Magnitude and Form	Pathogens Quantity Concentrations Time Locations	Containment of pathogens Management of activities Interdiction time
Release Mechanisms & Exposure Pathways	Accidents Intentional Acts Transport Routes Time Frames Loss and Gain Functions	Types of accidents & intentional acts Calculating the release and transport Interdiction of pathways
Receptors, Hosts, Vectors, etc.	Receptors: Humans/animals susceptibility, resistance, recovery, etc. Viable vectors and hosts	Estimate types and numbers of receptors Evaluate susceptibility, resistance, recovery, etc. Identify Viable vectors and hosts
Potential for Spread and Growth of Disease	Spatial and temporal models and analyses	Evaluate applicability, appropriateness, stability, and data availability of Spatial and temporal models
Prevention, Mitigation, and Response Strategies	Identification of safety and security controls, response methods and the characterization of risk	Profile the safety and security controls, response methods for the characterization of risk and for use in discrimination of sites

Exhibit 2 Overview of Agents Recommended for Study

Agent	BSL	Select Agent	Cat. A	Attributes	R_0	F
SARS-associated coronavirus	NIH Guideline: RG 2 (corona viruses) BMBL: BSL 2-treated diagnostic samples, BSL 2-enhanced untreated diagnostic samples, BSL 3-propagation	—	—	High transmissibility (respiratory) High morbidity High mortality (global CFR ~15%, 6.8% patients <60 yrs, 55% patients > 60 years)	2-3 (excludes super-spreading events)	-
Reconstructed 1918 pandemic influenza virus	NIH Guideline: Risk Group 2 (influenza viruses) BMBL: BSL 3 enhanced	√	—	Highly transmissibility (respiratory) High morbidity (~30% of world population infected in 1918) High mortality (CFR >2.5%, [<0.1% for other flu pandemics] ~50 million total deaths, peak death rates in young adults 20-40 years)	2-4 community based settings, 2-10 in confined settings	√
Bacillus anthracis	NIH RG 2 BSL 2 or BSL 3 (large scale; Aerosol potential)	√	NIH CDC	No human-to-human transmission Transmissability—Low 95% of cases are cutaneous Mortality—cutaneous form low with treatment, 20% if not treated; high mortality (45%) for pulmonary High mortality	Not known	√

Lassa fever virus	NIH: 4 BMBL: 4	√	NIH CDC	Arenavirus Highly transmissible in endemic areas (1° rodent-human) & 2° low for human-human during viremia – requires close blood contact). Requires close contact with rats or ingestion of rat meat. Morbidity: low to moderate - 80% mild; 20% severe. Mortality (no Rx): moderate - 12-23%; w/ Rx: 1-15%	Not known	
Rift Valley fever virus	NIH: 3 BMBL: 3	√	NIH	Bunyavirus Transmissibility: 1° infected animal blood (contact & aerosol), unpasteurized milk; 2° arthropods. No human-human transmission. Morbidity: low to moderate for humans – 1° requires vertebrate reservoir; 2° asymptomatic to mild infections. Mortality low: overall < 1%	Not known	
Francisella tularensis	3	√	NIH CDC	No human-to-human transmission Low morbidity Low mortality with treatment (4%)	Not known	
Andes hantavirus	NIH: 3 CDC: 2, 2+, 3, 4 (as a f/ of work performed)	–	NIH	Bunyavirus Causative agent of hantavirus pulmonary syndrome & hemorraghic fever w/ renal syndrome. Highly transmissible (by aerosol) in lab & in wild. Evidence for human-human transmission in 1 or 2 S. American outbreaks of Andes v.. Morbidity: Moderate to High? Mortality (HPS): High	Not known	

				(30–50%)		

South American Haemorrhagic fever virus (Junin)	NIH: 4 BMBL: 3*/4 (*w/ vaccine)	√	NIH CDC	Arenavirus (see Lassa) Highly transmissible in endemic areas (1° rodent-human) & 2° low for human-human during viremia – requires close blood contact. Morbidity: low to moderate – 90% mild; 10% severe. Mortality (no Rx): moderate – 15%; w/ Rx: 1-2%	Not known	
Tick-borne encephalitis complex (flavi) virus (Russian Spring and Summer encephalitis)	NIH: 4 BMBL: 4	√	–	Flavivirus Transmissibility: 1° arthropods 2° unpasteurized milk from infected animals. Morbidity low to moderate – 5% of cases severe. Mortality (no Rx): high – 5-35%; w/ Rx: 1-2%	TBE: < 1 (non-systemic TX) to ~1.3 (systemic TX)	

Yersinia pestis	3	√	NIH CDC	No human-to-human Low to moderate transmission from rodents to humans (flea-born); direct contact with infected tissue or fluid; respiratory droplets High morbidity High mortality (50 – 90% if untreated); Low to moderate mortality (15%) when diagnosed and treated	2º =1.3	√
Marburg virus	NIH Guidelines RG 4 BMBL BSL 4	√	NIH CDC	Low transmissibility (direct contact with infected blood or bodily fluids) High Morbidity High Mortality (CFR 23% in 1967 Europe, 83% 1998 DRC, 90% in 2004 Angola)	Not known	–
Ebola virus	NIH Guidelines RG 4 BMBL BSL 4	√	NIH CDC	Low transmissibility (virus shed in wide variety of bodily fluids, but low risk of transmission from fomites) High morbidity High mortality (CFR 95% Zaire EBOV, 55% Sudan EBOV)	Not known	–

Agents by Requestor

	Agent	Federal Court	State Court or Agency	EPA	Plaintiff	NRC Committee	Public Comment	Public Recognition
Agents Recommended for Study	**SARS-like coronavirus**	√	√	–	–	√	√	√
	1918 pandemic influenza virus	–	–	–	–	–	√	√
	Lassa fever virus	√ (gen, BSL-4)	–	–	–	√ (gen)	√ (gen)	–
	Rift Valley fever virus	–	–	–	–	√ (gen, vector)	√ (gen, vector)	–
	Francisella tularensis	–	–	–	–	√ (gen)	√ (gen)	√ in Boston
	Aerosolized *Bacillus anthracis*	–	√	–	–	–	√	√
	Andes hantavirus	–	–	–	–	√ (gen)	√ (gen)	+/-
	Yersinia pestis	–	–	–	–	√	√	√
	Junin haemorrhagic fever virus	–	–	–	–	–	–	–
	Tick-borne encephalitis complex virus (RSSE)	–	–	–	–	√ (gen)	√	–
	Marburg virus	–	–	–	–	–	–	–
	Ebola virus	√ (gen,	√	–	–	–	√	√

		BSL-4)						
Not Selected	**Highly pathogenic avian influenza virus (H5N1)**	—	—	—	—	—	√	√
	Variola major	—	√	—	—	—	√	√
	Mycobacterium tuberculosis	—	—	—	—	—	√	√
	Dengue virus	—	—	—	—	√	—	—
	Genetically modified agents	—	—	—	—	√	√	√

Overview of Scenarios by Type, Suggested Examples, and Source

Type of Scenario	Examples	Source of scenario
Mechanical or power failure	Lab equipment failure	NRC
	Loss of electrical power	Public
	Malfunction of solid and liquid waste disposal systems	Public
Transportation accident	Transportation accident	Federal Court
Security failure	Site security failure	NRC
	Personnel security failure	NRC
Release via fomites or vectors	Fomites contaminated with transmissible agents	Public
	Release of vector-borne agent	NRC, Public
Human error	Procedural errors resulting in inadvertent infection (e.g., mislabeled tubes)	NRC, Public
	Infection not diagnosed early and spreads in community, esp. via public transportation	Public
Malevolent action	Malevolent actions	NRC, State Court
	Suicide bomber, airplane attack, truck with explosives, fire	Public
	Disgruntled or deranged lab worker spreads agents in community	Public

Exhibit 3 Draft Overview of Agents, Scenarios, and Analytic Methods for Case Studies

Intrinsic Agent Attributes Considered	
Infectivity	Pathogenicity
Primary infection rate	Mortality rate
Primary routes of human infection	Reservoir (if known)
Transmissibility	Vector (if any)
Secondary transmission	Treatment(s)
Tertiary transmission	Availability
Incubation period	Effectiveness
Infection period	
Attributes of Agents to be Studied	
Highly transmissible, highly pathogenic, and with a higher case fatality rate	
Highly transmissible, pathogenic, and with a lower case fatality rate	
Poorly transmissible but highly pathogenic, and with a higher case fatality rate	
Vector-borne and relevant to the sites to be assessed	
Sufficient epidemiologic data should be available	
Agents should be recognized public health threats, i.e., designated as a select agent or category A agent, likely to be studied in the NEIDL, and/or recognized by the public as an agent of concern	
Agents Proposed for Study	
BSL-3	BSL-4
SARS-associated coronavirus	Junin haemorrhagic fever virus s,c
1918 pandemic influenza virus s	Tick-borne encephalitis complex (Russian spring
Yersinia pestis s,c	and summer encephalitis) virus s
Francisella tularensis s,c	Lassa fever virus s,c
Bacillus anthracis s,c	Marburg virus s,c
Rift Valley fever virus s,c	Ebola virus s,c
BSL-3 or 4	s = Select Agent, C = Category A agent
Andes hantavirus s,c	
Types of Scenarios for Study	
Accidental release/exposure due to human error (e.g., needle-stick, aerosolization, mishandling of samples leading to inappropriate handling)	
Transportation mishap	
Escape of infected insect/arthropod	
Internal breach of security, such as a release/exposure due to malevolent actions (disgruntled lab worker)	
External breach of security, such as a terrorist attack	
Highly unlikely but still credible high consequence event	
Analytic Methodology for Studies	
Quantitative analysis for all cases	
Qualitative analysis, as data permits, using most appropriate modeling method	
Susceptible, Infected, Recovered	
Spatially and Temporally Explicit Agent-based) will depend on the quality and quantity of available data	
Risk of agent release	
Probability of occurrence	
Any uncertainty in critical parameters used	

For any value selected for use, the range of published values
Available public health interventions
Comparative risks at urban, suburban, and rural sites
What happens when safety measures and emergency plans do and don't work